

# Foundations of Cardiometabolic Health Certification Course

**Certified  
Cardiometabolic  
Health Professional  
(CCHP)**



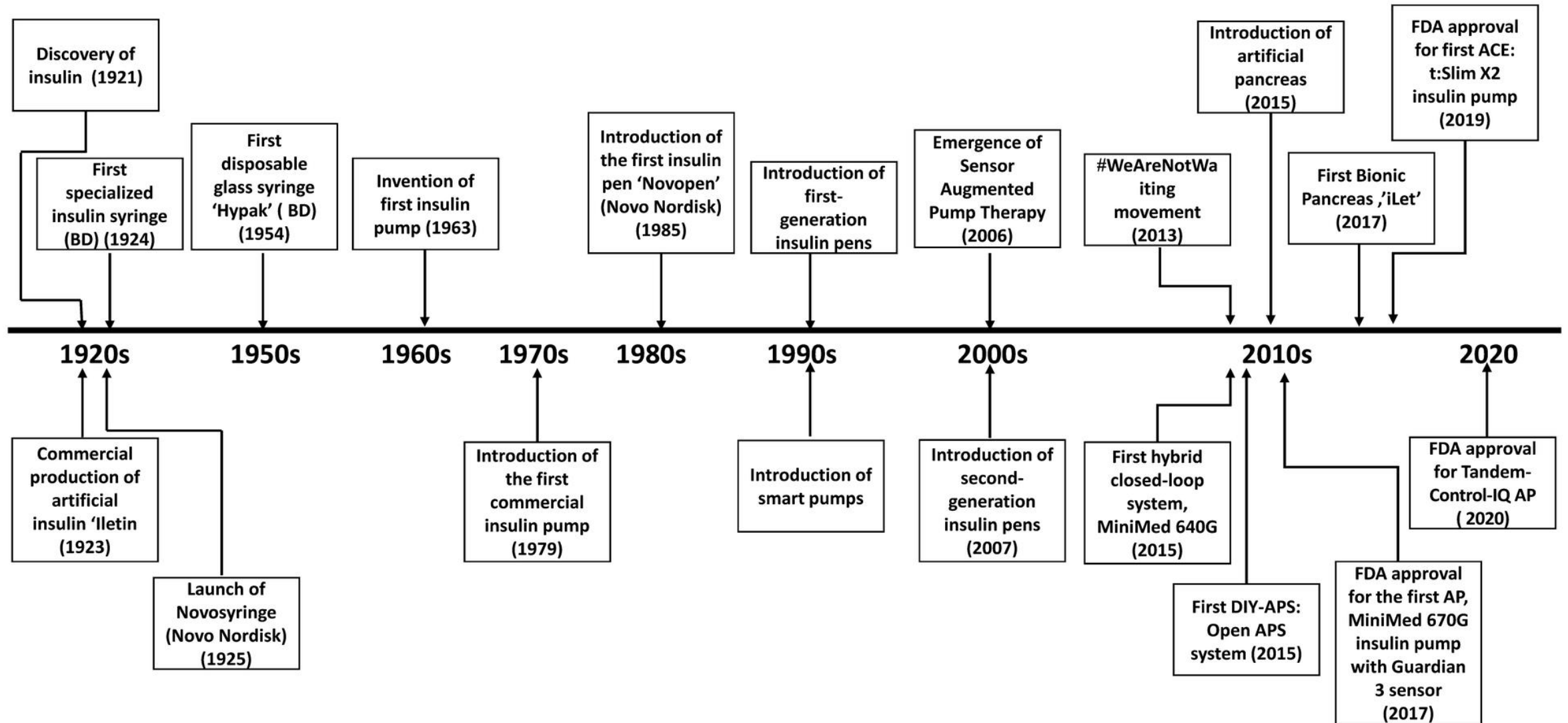
## Connected Insulin Pens in 2023 and Beyond

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University of Colorado

# Disclosure Statement

- Advisory Boards: Sanofi, Medscape, LifeScan, DKSH Singapore, and NovoNordisk
- Co-Director, Diabetes Dialog: 3-days educational program for Endocrine Fellows sponsored by many industries
- Speaking: Dexcom, Insulet, Tandem Diabetes Care and Embecta
- Research Grants: Eli-Lilly, NovoNordisk, Insulet, Tandem Diabetes Care, Dexcom, Alexion, NIH and JDRF

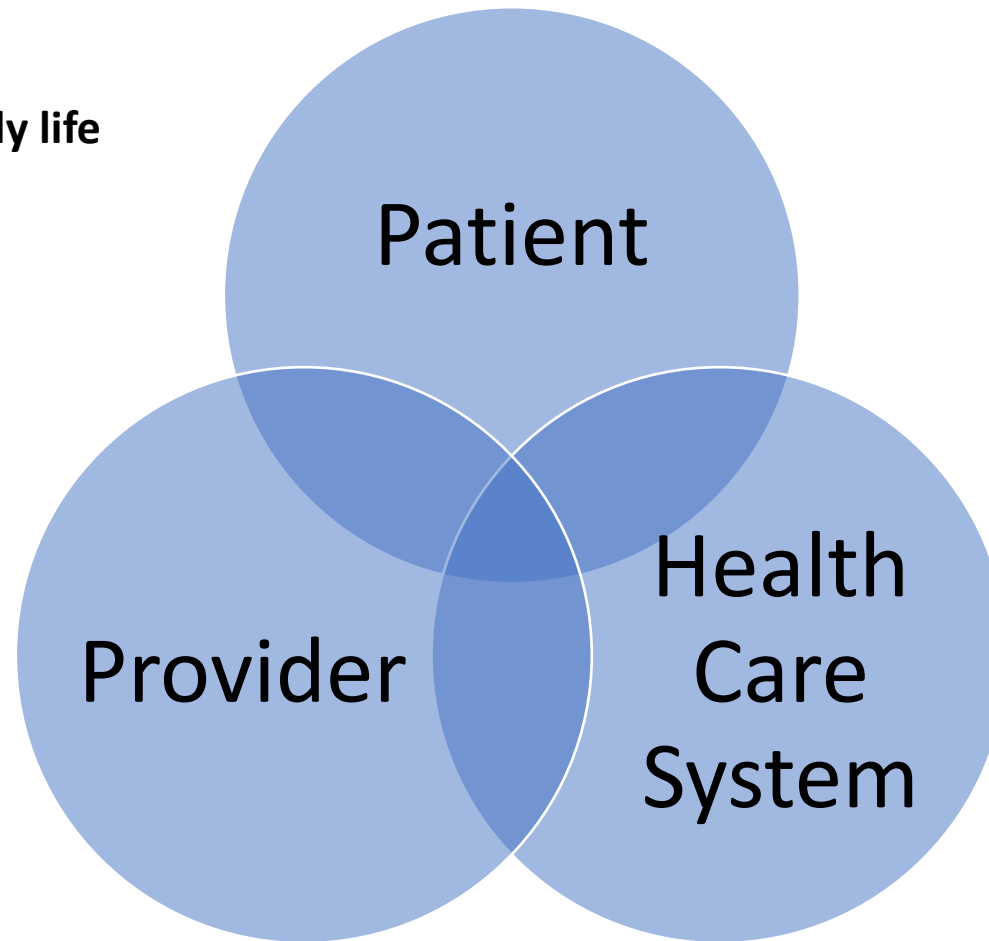
# Evolution of Insulin Delivery Systems



# Case

- 74-year-old female with 28 years of type 1 diabetes
- MDI with insulin glargine U100 and Insulin Lispro
- A1c of 7.6%
- Mild NPDR
- Other medical conditions: hypothyroidism, hypertension, dyslipidemia, and BL hip arthritis
- Retired and enjoys traveling
- Didn't like pump in the past

- **Difficulty remembering**
- **Injection site reactions**
- **Fear of hypoglycemia**
- **Interference with daily life**
- **Cultural**



- **Lack of familiarity with devices**
- **Bias**
- **Therapeutic/Clinical inertia**

- **Complex health care system**
- **Time consuming**
- **Cost**

# Missed Insulin Doses

DIABETES TECHNOLOGY & THERAPEUTICS  
Volume 23, Number 12, 2021  
Mary Ann Liebert, Inc.  
DOI: 10.1089/dia.2021.0164

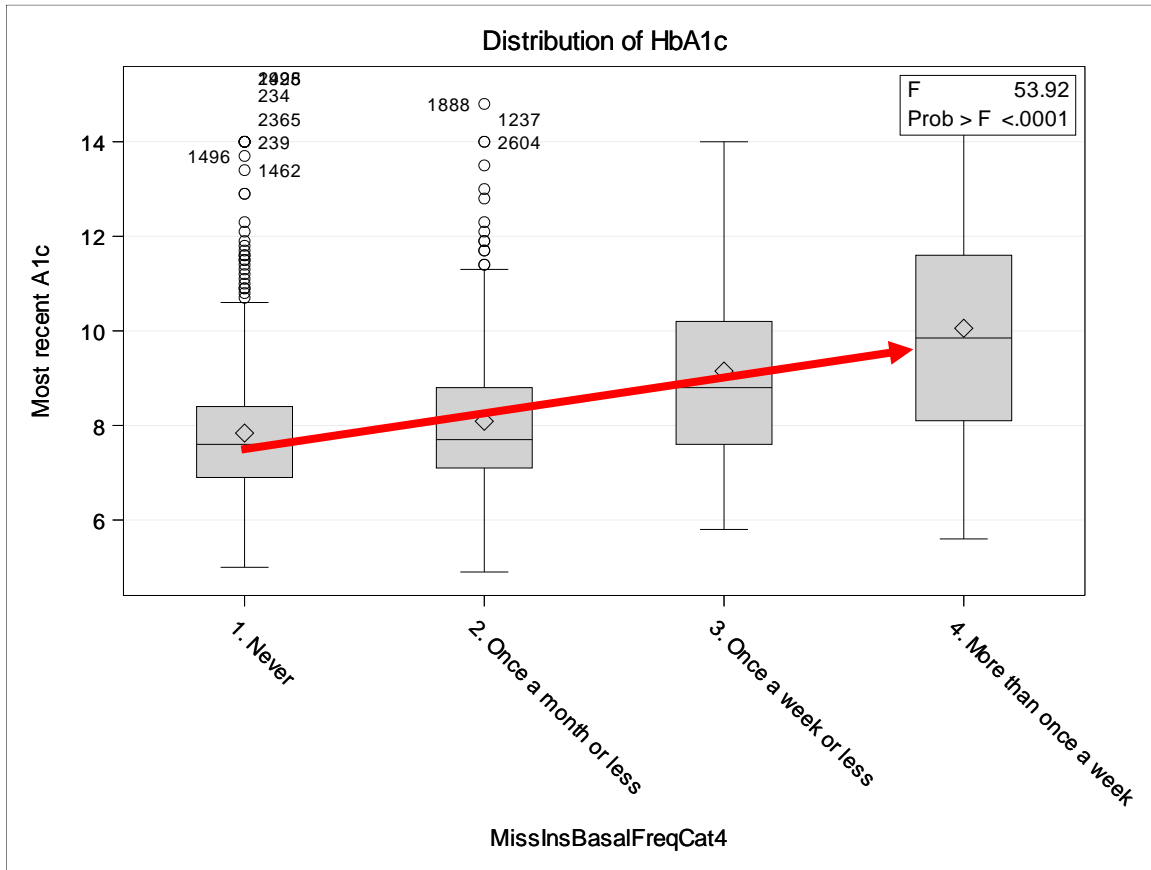


REVIEW ARTICLE

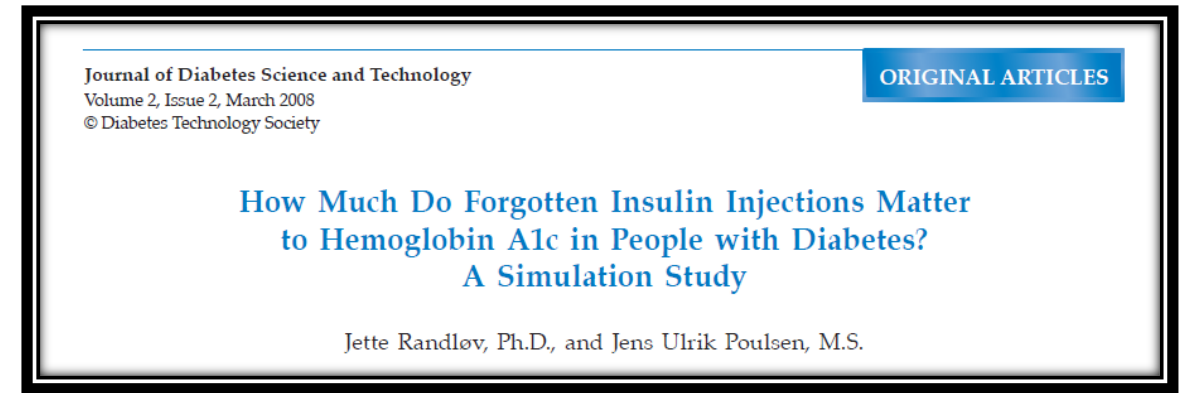
## Missed and Mistimed Insulin Doses in People with Diabetes: A Systematic Literature Review

Susan Robinson, PhD,<sup>1</sup> Rachel S. Newson, PhD,<sup>2,1</sup> Birong Liao, PhD,<sup>3</sup>  
Tessa Kennedy-Martin, MSc,<sup>1</sup> and Tadej Battelino, MD, PhD<sup>4</sup>

- 10-59% of individuals with T1D reported missing at least 1 bolus dose per week
- 10-30% of individuals with T1D reported missing at least 1 basal dose per month
- 1-30% of individuals with T2D reported missing at least 1 basal insulin dose per month



Unpublished data



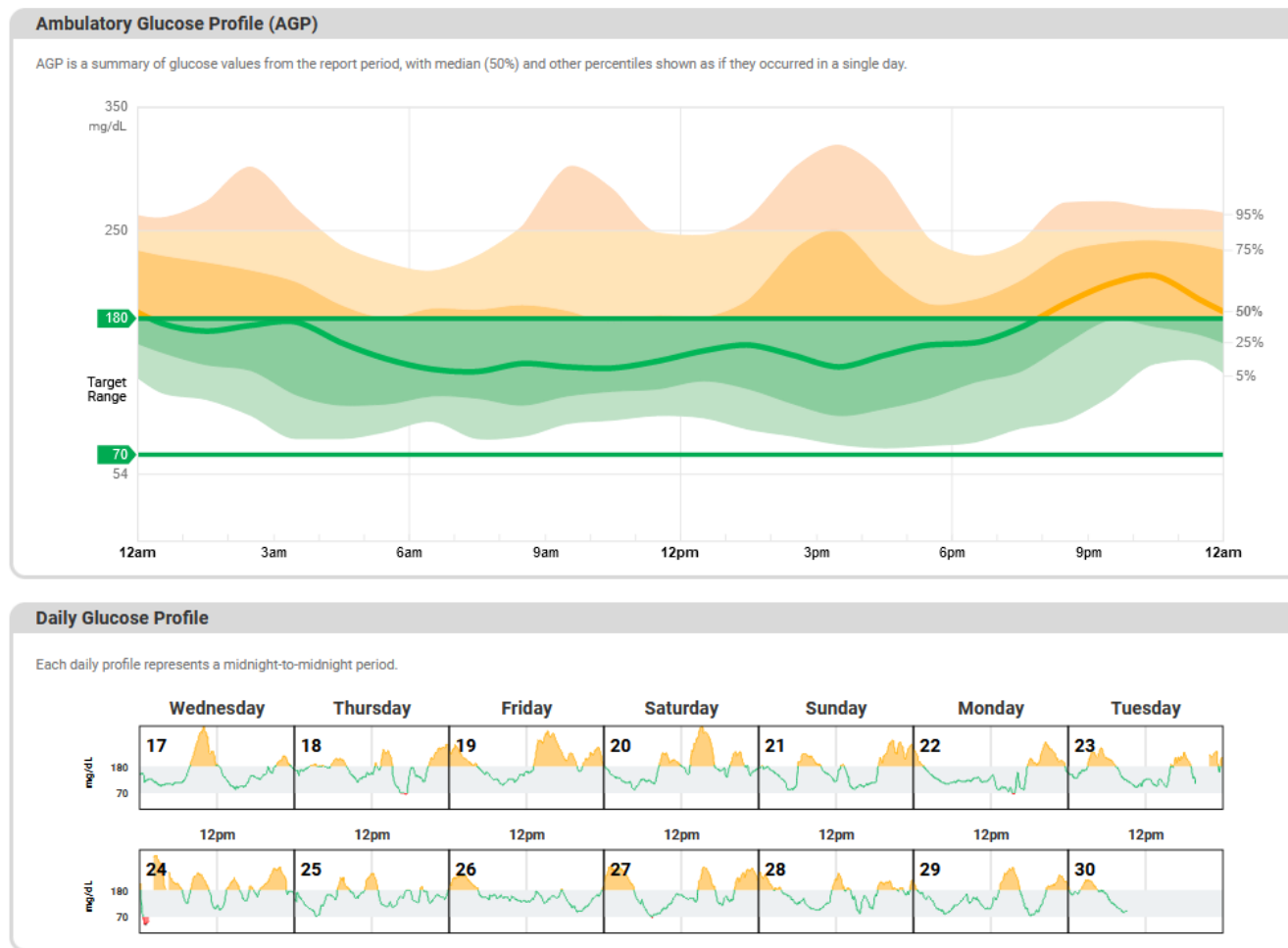
~ 2 bolus doses per week would lead to increase in A1c by 0.3-0.4%

~30% of missed insulin doses would lead to increase in A1c by 1.8%.



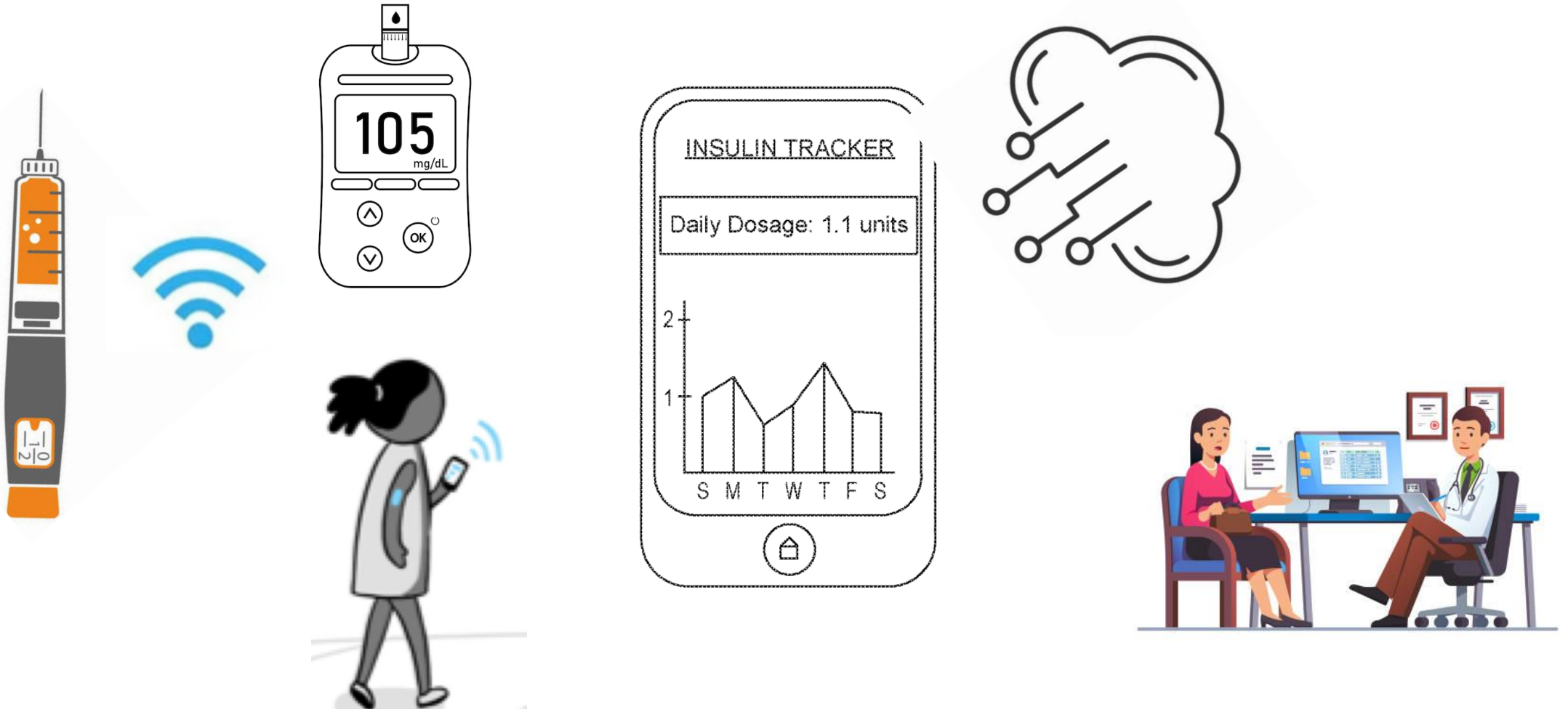
# Insulin dosing information: A missing link

A1c of 7.6%





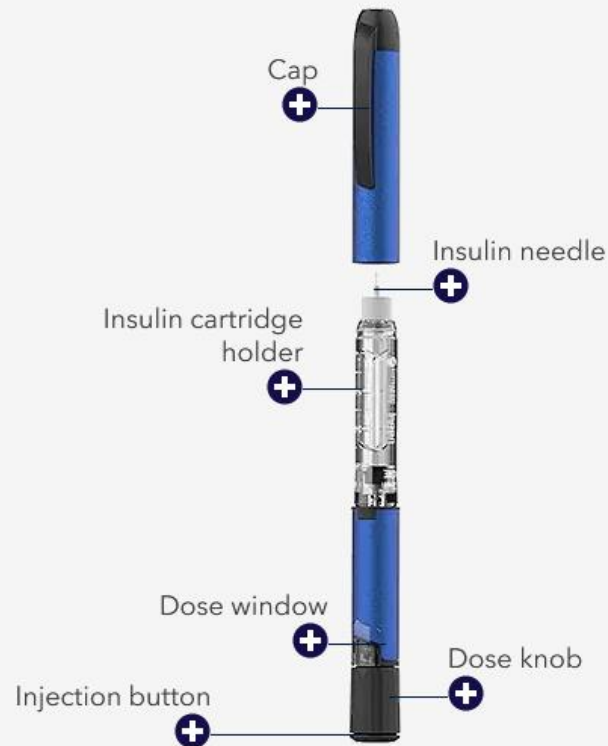
# Connected Insulin Pen Concept



## **Currently Available Connected Pens in the US**

# InPen

## The pen



## The app



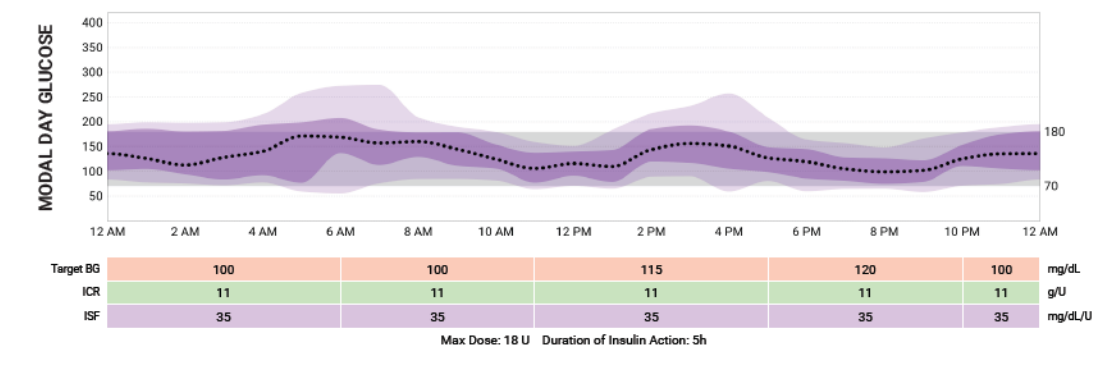
- ✓ Reusable pen injector for by people with diabetes under the supervision of an adult caregiver, or by a patient age 7 and older for the self-injection
- ✓ Insulin lispro U-100, insulin aspart U-100, and fast-acting insulin aspart U-100 3.0 mL cartridges
- ✓ Insulin dose calculation based on carb ratio, correction factor, and active insulin time
- ✓ Can be used for fixed doses
- ✓ Insulin dose tracking, reminders
- ✓ Used with Dexcom G6 and Medtronic Guardian 3 CGM
- ✓ Downloadable reports that can be shared
- ✓ Once a year replacement

# Interpretation of InPen Data

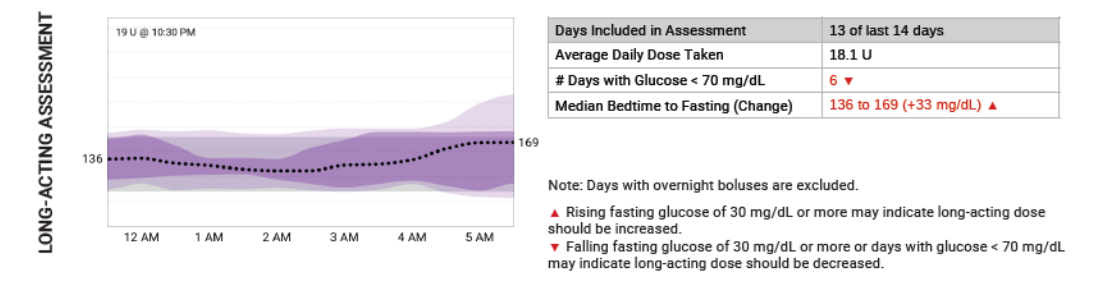
Insulin statistics →



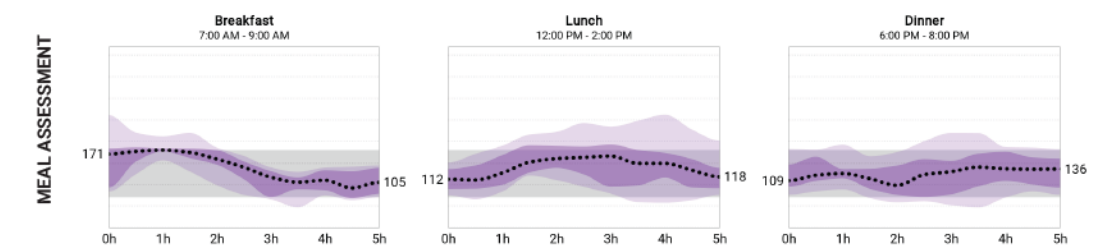
AGP →



Long-acting assessment →



Meal assessment →



# Bigfoot Unity



- Approved for age 12 and above
- Smart Pen cap
- Basal (black cap) and bolus (white cap)
- Bolus pen cap can be used with Freestyle Libre 2 CGM (pen can scan the sensor)
- Clinic based prescription model
- No half units
- Compatible with almost all insulin pens
- Rechargeable

# Bigfoot Clinic Hub

Reporting very similar to AGP →

Insulin dose →



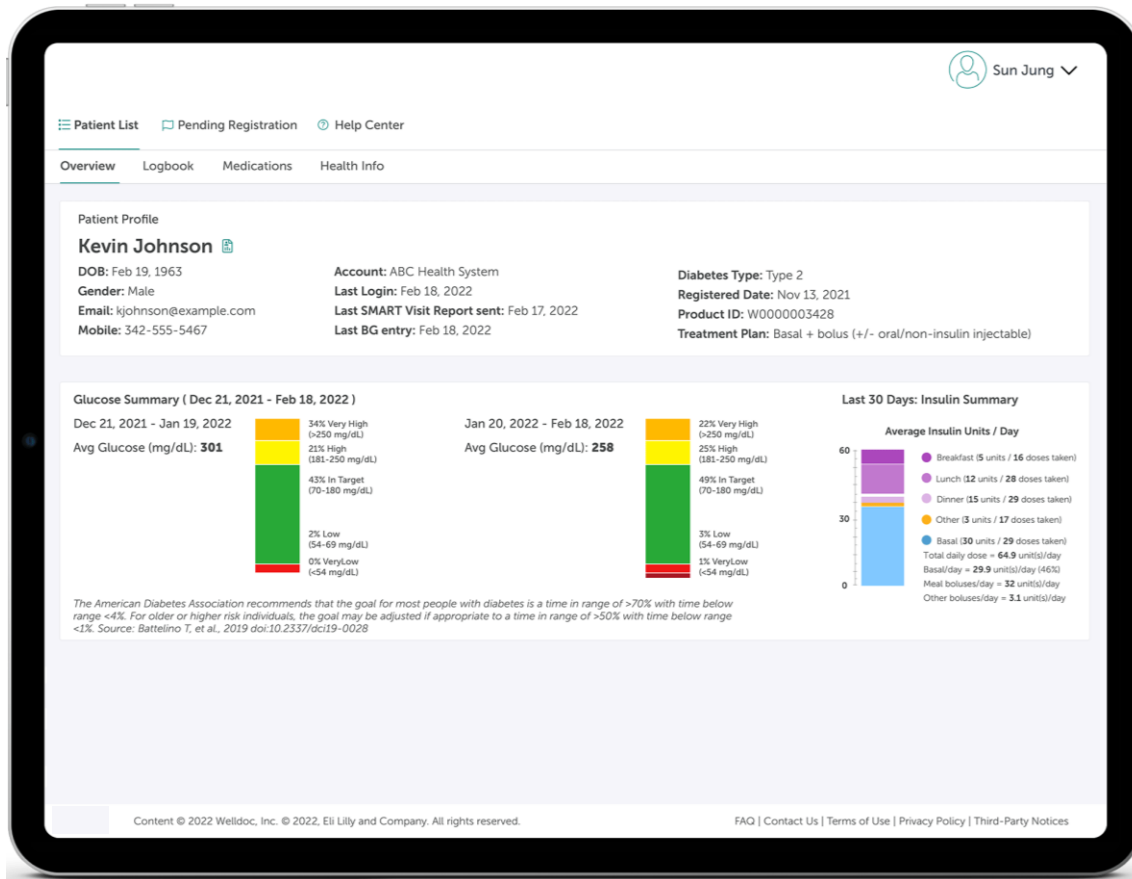
# Lilly Tempo



- Indicated for age 18 and above
- Reusable smartpen cap
- Works with Lilly U100 insulins (glargine, lispro, fast-acting lispro-aabc)
- Connects to its app with Bluetooth
- Integration with BGMs and CGM (Dexcom)
- Battery up to 8 months
- Battery life indicator (green-okay, Amber-low battery)
- No half units or dosing recommendations



# Tempo Insight



# Connected Pen caps

## The InsulCheck Range

InsulCheck  
CLASSIC



InsulCheck  
CONNECT



InsulCheck  
DOSE



GET

**“Advantages and Disadvantages of Connected Insulin Pens in Diabetes Management”**

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**Short Title:** Connected Insulin Pen Review

**Four keywords describing manuscript:** connected insulin pens, pen caps

Word Count (excluding references and figure legends): 4,446

# Evidence on connected pens

Study, year	Device	Sample Size	Type 1 or type 2 diabetes	Type of Trial	Primary Outcome	Secondary Outcome
Adolfsson (2020) <sup>26</sup>	NovoPen 6	94	T1D	Prospective, proof-of concept study	Time in Range (P < 0.001)	Missed bolus doses (P = 0.1352), Time Above Range (P = 0.003), Time Below Range (P = 0.005)
Gomez-Peralta (2020) <sup>30</sup>	Insulclock	16	T1D	Randomized pilot study	Time in Range (P = 0.038)	Missed bolus doses, Time Above Range (P = 0.0026), Time Below Range
Jendle (2021) <sup>19</sup>	NovoPen 6	94	T1D	Prospective, proof-of concept study (continuation of Adolfsson et al. 2020)	Cost effectiveness, Time in Range	Mortality, Quality of Life, Time Above Range, Time Below Range

Vigersky (2021) <sup>28</sup>	InPen	529	T1D or T1D	Observational study	Time in Range (P < 0.05)	Time Above Range, Time Below Range, Total insulin doses (all P<0.05)
Ekberg (2022) <sup>27</sup>	NovoPen 6	32	T1D	Prospective, proof-of-concept study	Missed bolus doses (P < 0.001)	Time in Range (p=0.005), Time Above Range (p=0.002), Time Below Range (ns)
Galindo (2023) <sup>29</sup>	Insulclock	80	T2D	Randomized, cross over pilot	Missed bolus doses (ns)	A1c (P = 0.006), Mean glucose
Chien (2023) <sup>20</sup>	InPen	1,681	T1D or T2D	Retrospective, real-world analysis	Number of severe hypoglycemia episodes (P = 0.008)	Cost savings
Baliga (2023) <sup>31</sup>	Bigfoot Unity	58	T1D or T2D	Retrospective, real-world analysis	A1c (P < 0.001)	Time in Range (P < 0.05), Time Above Range (P < 0.05), Time Below Range, Average glucose (P < 0.05)

# My Opinion

- Connected pens are very helpful to view insulin dosing and allows clinicians to optimize diabetes care
- Helpful to patients in remembering and calculating insulin dose. Also, it may help to avoid insulin stacking.
- Connected pen without CGM may have limited utility
- Connected insulin pens would be beneficial in selective patients
  - *Those who are missing insulin often*
  - *Higher A1c*
  - *Problematic hypoglycemia and insulin stacking issues*